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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/091,281	03/06/2002	Vincent Raymond	13587.338	7473

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EXAMINER

TUNG, JOYCE

ART UNIT PAPER NUMBER

1637

DATE MAILED: 05/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.		Applicant(s)	
	10/091,281		RAYMOND ET AL.	
	Examiner		Art Unit	
	Joyce Tung		1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 February 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-51 is/are pending in the application.
- 4a) Of the above claim(s) 1-21 and 41-51 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 22-40 is/are rejected.
- 7) ☒ Claim(s) 24,34 and 39 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>03062002</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of group IV claims 22-40 with SEQ ID NO: 1 in Paper No. 02032004 is acknowledged. The traversal is on the ground(s) that Groups I to Group VII should be examined together and at least Group IV to VI should be examined together. This is not found persuasive because as indicated by the Office action mailed 12/03/2003, these groups have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). Thus, they are different inventions.

The response further argues that SEQ ID NO: 1 is a *Homo sapiens* nucleotide sequence of optineurin promoter and SEQ ID NO: 3 to 463 are *Homo sapiens* which correspond to partial subsequences of SEQ ID NO: 1. However, although SEQ ID NO: 3 to 463 correspond to partial subsequences of SEQ ID NO: 1, each nucleic acid sequence has its own nucleotide sequence which presents different invention from each other. Thus, they are different inventions.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 1-21 and 41-51 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected group, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 02032004 as discussed above. Claims 22-40 are pending.

Claim Objections

3. Claims 24, 34 and 39 are objected to because of the following informalities: These claims do not have an elected nucleic acid sequence from SEQ ID NO: 3 through 463. Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 22-40 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In analysis of the claims for compliance with the written description requirement of 35 U.S.C. 112, first paragraph, the written description guidelines note regarding genus/species situations that "Satisfactory disclosure of a 'representative number' depends on whether one of skill in the art would recognize that the applicant was in possession of the necessary common attributes or features of the elements possessed by the members of the genus in view of the species disclosed." (See: Federal Register: December 21, 1999 (Volume 64, Number 244), revised guidelines for written description.)

All of the current claims encompass a genus of nucleic acids, which is a polymorphism in a promoter region of the optineurin gene, which are not disclosed in the specification. The genus includes an enormous number of polymorphisms for which no written description is provided in the specification. This large genus is represented in the specification by only the polymorphisms listed in Table 1 (See pg. 18 of the specification) for which data is provided demonstrating an

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association with the identification of risk for developing glaucoma or a progression from an ocular hypertensive state and may be associated with therapeutic responsiveness (see pg. 17). Thus, applicant has express possession of only particular polymorphisms listed in Table 1, in a genus, which comprises hundreds of millions of different possibilities. Here, no common element or attributes of the sequences are disclosed which would permit selection of sequences as polymorphisms. No structural limitations or requirements which provide guidance on the identification of sequences which meet the functional limitations of associating a polymorphism for diagnosing glaucoma by detecting a polymorphism in a promoter region of the optineurin gene is provided. Further, these claims expressly encompass all the different possible allelic variants including insertions, deletion, substitutions and transversions at thousands of different sites. No written description of alleles, of upstream or downstream regions containing additional sequence, which are associated with the polymorphism in a promoter region of the optineurin gene.

6. Claims 22-40 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the marker which is capable of detecting a SNP set forth in Table 2, does not reasonably provide enablement for using any marker nucleic acid molecule having a nucleic acid sequence that specifically hybridizes to a sequence selected from the group consisting of SEQ ID NO: 1 and complement thereof, and a complementary nucleic acid molecule obtained from a sample. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

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Factors to be considered in determining whether a disclosure meets the enablement requirement of 35 USC 112, first paragraph, have been described by the court in *In re Wands*, 8 USPQ2d 1400 (CA FC 1988). *Wands* states at page 1404.

“Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized by the board in *Ex parte Forman*. They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.”

The nature of the invention

The claims are drawn to a method for diagnosing glaucoma in a sample obtained from a cell or a body fluid by detecting a polymorphism in a promoter region of the optineurin gene comprising using a marker nucleic acid molecule having a nucleic acid sequence that specifically hybridizes to a sequence selected from the group consisting of SEQ ID NO: 1 and a complement thereof, and a complementary nucleic acid molecule obtained from a sample under nucleic acid hybridization condition, permitting the hybridization and detecting the presence of the polymorphism. The invention is in a class of invention, which has characterized as “the unpredictable arts such as chemistry and biology.” *Mycogen Plant Sci., Inc. v. Monsanto Co.*, 243 F.3d 1316, 1330 (Fed. Cir. 2001).

The breadth of the claims

The claims encompass any nucleic acid selected from the group consisting of the 5054 nucleotides of SEQ ID NO: 1 which will be used as a marker nucleic acid. Thus, the claims claim 5054 different nucleic acids markers. These species even have less utility in the very large

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genus for diagnosing glaucoma via detecting a polymorphism in a promoter region of the optineurin gene.

Quantity of Experimentation

The quantity of experimentation in this area is extremely large since determination of a use for the many sequences would require, initially, studies to demonstrate some utility or use. This study is an inventive, unpredictable and difficult undertaking in itself, and utility would need to be demonstrated by some association such as an epidemiological study. This would require years of inventive effort, with each of the many intervening steps, upon effective reduction to practice, not providing any guarantee of success in the succeeding steps.

The unpredictability of the art and the state of the prior art

The art in biotechnology, as relates to the association of diseases with particular genes, is highly unpredictable. For example, In Rezaie et al (Science, 2002, Vol. 295(8)), Rezaie et al. indicate that the identification of *OPTN* as an adult-onset glaucoma gene provides an opportunity to screen the general population because *OPTN* mutations are a contributing factor in patients with normal pressure glaucoma (NPG) (See pg. 1079, column 2, last paragraph). However, Rezaie et al. do not disclose a nucleic acid marker having a nucleic acid sequence that specifically hybridizes to a sequence selected from the group consisting of SEQ ID NO: 1 and a complement thereof, and a complementary nucleic acid molecule obtained from a sample.

Working Examples

The specification has a working example of the identification of SNPs in the optineurin promoter. The method applies genomic DNA from 23 individuals sequenced (See pg. 111-113). Nevertheless, the method does not apply the marker nucleic acid molecule having a nucleic acid

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sequence that specifically hybridizes to a sequence selected from the group consisting of SEQ ID NO: 1 and a complement thereof and a complementary nucleic acid molecule obtained from a sample.

Guidance in the Specification.

The specification provides no guidance on uses for the marker nucleic acid.

Level of Skill in the Art

The level of skill in the art is deemed to be high.

Conclusion

In the instant case, as discussed above, the level of unpredictability in the art is high (see Rezaie et al.), the specification provides one with no written description or guidance that leads one to a reliable method of using the marker nucleic acids for diagnosing glaucoma in a sample obtained from a cell by detecting a polymorphism in a promoter region of the optineurin gene. One of skill in the art cannot readily anticipate the effect of a change within the subject matter to which the claimed invention pertains. Thus given the broad claims in an art whose nature is identified as unpredictable, the unpredictability of that art, the large quantity of research required to define these unpredictable variables, the lack of guidance provided in the specification, the absence of any working examples and the negative teachings in the prior art balanced only against the high skill level in the art, it is the position of the examiner that it would require undue experimentation for one of skill in the art to perform the method of the claim as broadly written.

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 22-40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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a. Claims 22-40 are vague and indefinite because of the phrase “a complementary nucleic acid molecule obtained from a sample” in claim 1, 32 and 40. It is unclear whether or not the complementary nucleic acid from a sample is complementary to the marker nucleic acid molecule. Clarification is required.

Summary

9. No claims are allowable.

10. Any inquiries concerning this communication or earlier communications from the examiner should be directed to Joyce Tung whose telephone number is (703) 305-7112. The examiner can normally be reached on Monday-Friday from 8:00 AM-4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached at (703) 308-1119 on Monday-Friday from 10:00 AM-6:00 PM.

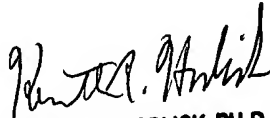
Any inquiries of a general nature or relating to the status of this application should be directed to the Chemical/Matrix receptionist whose telephone number is (703) 308-0196.

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11. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Art Unit 1637 via the PTO Fax Center located in Crystal Mall 1 using (703) 305-3014 or 308-4242. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Joyce Tung

April 15, 2004


KENNETH R. HORLICK, PH.D.
PRIMARY EXAMINER
5/3/04